



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,964	07/15/2003	Satoshi Wada	029650-142	5917

7590 08/21/2007
BURNS, DOANE, SWECKER & MATHIS, L.L.P.
P.O. Box 1404
Alexandria, VA 22313-1404

EXAMINER

JACKSON, BRANDON LEE

ART UNIT	PAPER NUMBER
----------	--------------

3772

MAIL DATE	DELIVERY MODE
-----------	---------------

08/21/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/618,964

Applicant(s)

WADA ET AL.

Examiner

Brandon Jackson

Art Unit

3772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 9-15 and 17-28 is/are pending in the application.
- 4a) Of the above claim(s) 21-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-15, 17-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 10/17/2003.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

DETAILED ACTION

This action is in response to arguments/amendments filed 6/13/2007. Currently, claims 1-7, 9-15, 17-28 are pending in the instant application. Claims 21-28 remain withdrawn to a non-elected invention.

Response to Arguments

Applicant's arguments with respect to claims 1-20 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5, 7, 9-15, 17-18, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Itonaga et al. (U.S. Patent 6,336,901) in view of Fareed (U.S. Patent

Art Unit: 3772

5,295,951) and Makower et al. (US Patent 5,569,297). Itonaga discloses a cuff device (30) comprising a flexible band (13) that is adapted to or is capable of being wrapped around a limb (1) where bleeding is to be stopped (col. 6, lines 58-59), a hook and loop fastener liner that is a means for (col. 6, lines 16-17) securing the band in a wrapped stated, a main balloon (11) that inflates (col. 6, lines 33-35) when fluid is introduced therein, a pressing member (12) that overlaps the main balloon (11). The pressing member (12) presses against the main balloon (11) substantially towards the middle of the limb (1). The pressing member (12) is a secondary balloon (col. 6, lines 6-7) that presses against the main balloon (11) under the influence of pressure by the fluid. The pressing member (12) inflates (col. 6, lines 38-40) with the introduction of fluid therein. The pressing member (12) and the main balloon (11) have three-way cock system (61) for communication (figs. 7A-7C). The pressing member (12) and main balloon (11) are positioned near one end of the curved plate (fig. 3). The main balloon can also be positioned near the center portion of the top of the flexible band (13) and have a smaller radius of curvature (fig. 2). The main balloon (11) and the pressing member (12) are only connected on one side of the band (figs. 1-4). The term "connected" has been given its broadest, most reasonable definition; which is to be joined together through contact. With respect to claims 15, 18, and 20, these limitations are intended use and the Itonaga device (30) would be capable to perform the functions of decreasing pressure or deformation over intervals of time to certain inflation percentages. Itonaga fails to disclose a curved plate having an inner peripheral side, where the plate is made of a material more rigid than the band; and wherein the main balloon is at a position

Art Unit: 3772

deviated to one end of the curved plate in the lengthwise direction of the band.

However, Fareed discloses a compression band (50) with a curved plate (56) having an inner peripheral (fig. 5) and being inflexible (col. 4, lines 41-43), an inflatable balloon (55), and the ability to apply pressure to a limb (fig. 4). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the Itonaga cuff (30) to have a curved plate, as taught by Fareed, in order to provide transaxial counter compression to the limb and prevent movement of the pressing member and main balloon.

Itonaga/Fareed does not teach a pressure balloon on one side of the curved plate. However, Makower teaches a vascular compression device (fig. 3) comprising a curved plate (40), a band (42), and a pressure element (46) positioned on one side of the curved plate (40). Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the Itonaga/Fareed device to have the pressure balloons on one side of the plate because the localized pressure can be pinpointed to almost any location on a limb while minimizing patient discomfort.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Itonaga et al. (U.S. Patent 6,336,901) and Fareed (U.S. Patent 5,295,951) and Makower et al. (US Patent 5,569,297), further in view of Yamakoshi et al. (U.S. Patent 6,694,821).

Itonaga/Fareed/Makower substantially discloses the claimed invention, see claim 1 rejection above. Itonaga/Fareed/Makower fails to disclose that the pressing member is smaller than the main balloon. However, Yamakoshi teaches a cuff (10) with a pressing member (14) smaller than the main balloon (16). Therefore, it would have been obvious

Art Unit: 3772

to one of ordinary skill in the art to modify the pressing balloon of the Itonaga/Fareed/Makower device to make the member smaller than the main balloon in order to apply pressure towards the artery rather than the whole limb.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Itonaga et al. (U.S. Patent 6,336,901) and Fareed (U.S. Patent 5,295,951) and Makower et al. (US Patent 5,569,297). Itonaga/Fareed/Makower substantially discloses the claimed invention, see claim 15 rejection above. Itonaga/Fareed/Makower fails to disclose a tensile modulus of at most 10 gf/mm². However, Applicant does not disclose that a tensile modulus of at most 10 gf/mm² solves any stated problem or provide any specific advantage; therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to make the Itonaga/Fareed/Makower device of a material with a tensile modulus at the most 10 gf/mm². The specified tensile modulus is a mere design consideration and does not patentably distinguish the claimed invention.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Akerfeldt et al. (US Patent Application Publication 2004/0122469), Stalemark et al. (US Patent 6,827,727), Dunton (US Patent 37,156), Akerfeldt (US Patent Application Publication 2004/0049214).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

Art Unit: 3772

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon Jackson whose telephone number is (571)272-3414. The examiner can normally be reached on Monday - Friday 8-5:30.

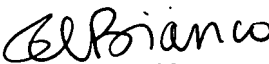
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571)272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3772

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brandon Jackson
Examiner
Art Unit 3772

BLJ


PATRICIA BIANCO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700
